

APR 19 2011

510(K) SUMMARY

EarlySense Ltd.

EverOn Central Display System (CDS)

7.1.1 Applicant's Name:

EarlySense Ltd.
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7.1.2 Contact Person:

Dalia Argaman
EarlySense Ltd.
12 Tzvi Street.
Ramat Gan 52504, Israel
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Fax: +972-3-752-2340
Mail: Dalia.Argaman@EarlySense.com

7.1.3 Date Prepared:

Feb. 15, 2011

7.1.4 Trade Name:

EverOn Central Display Station

7.1.5 Classification Name:

System Network and communication, physiological monitors	
Medical Specialty / Panel:	Cardiovascular
Product Code:	MSX
Class:	II
Regulation Number:	870.2300

7.1.7 Predicate Devices

The EverOn Central Display Station (CDS) is substantially equivalent to the following:

1. Masimo Patient Safety Net (PSN) system, K071047 (Masimo Corporation), Regulation number: 21 CFR 870.2300, System Network and communication, Physiological Monitors; Product code: MSX
2. EverOn Central Display Station (CDS) K100376 (EarlySense Ltd) Regulation number: 21 CFR 870.2300, System Network and communication, Physiological Monitors; Product code: MSX

7.1.8 Device Description:

The EverOn Central Display Station (CDS) is intended to communicate with multiple EverOn bed-side monitoring devices and remotely display the information as displayed on multiple individual bed side monitoring units, on a central screen. The communication can be performed either via standard wired or via wireless LAN communication.

The transmitted information from Bed-side to CDS includes alert information and physiological parameters. The CDS can also format the alert information as obtained from bed-side units into a message that can be transmitted to external devices that can communicate with the CDS via standard TCP/IP port. Data and report files (.CSV and .PDF) generated at the bed-side units can be retrieved via the CDS by the user and can be downloaded and / or sent for printing from the CDS. The CDS includes standard hardware (PC, communication and IT hardware). EarlySense develops the application software which is used on the system's PC computer (Central Display Station).

7.1.9 Intended Use:

The EverOn Central Display Station (CDS) is intended to provide secondary display of the information as displayed on multiple individual bed side monitoring units, on a central remote screen. The EverOn CDS is not intended to replace any part of the bed-side patient monitoring procedures. The system can be used in hospitals or hospital type and clinic environment.

7.1.10 Performance Standards:

The EverOn Central Display Station follows and complies with the following standards:

- Programmable electrical medical system Requirements for safety. EN/IEC 60601-1-4 (2000)
- ANSI / AAMI/ ISO – Application of risk management to medical devices. ISO 14971-1 (2007)
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff, FDA, CDRH, 11/1/02
- IEC 62304:2006 Software Development Life Cycle for medical devices.
- IEC 60812 Ed.2:2006. Analysis technique for system reliability - Procedure for failure modes and effects analysis (FMEA)

7.1.12 Performance Data & Substantial Equivalence

The EverOn CDS with wireless communication capability is substantially equivalent in all aspects e.g., technological characteristics, mode of operation, performance characteristics, intended use, etc., to the Masimo Patient Safety Net (PSN) (K071047) and is identical in all aspects to the EverOn Central Display Station (K100376).

The modification:

The CDS software was modified to include the capability of wireless communication. The modified System was subjected to the following:

- Hazard analysis was performed, including risk analysis, level and solutions performed for the entire system and software.
- The modified software went through comprehensive software verification and validation testing.
- Full load bench testing was performed to establish the correct communication between bed-side and CDS and establish the correct performance of the system with wireless communication.

Based on the design verification and validation processes performed as a result of risk assessment and results of the testing performed, EarlySense Ltd. believes that the CDS with wireless communication capability is substantially equivalent to the cleared EverOn CDS where communication utilized only standard wired LAN, without raising new safety and/or effectiveness issues.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

EarlySense Ltd.
c/o Ms. Dalia Argaman
12 Tzvi Street.
Ramat Gan 52504, Israel

APR 19 2011

Re: K110521

Device Name: EverOn Central Display Station (CDS) with Wireless Communication
Regulation Number: 21 CFR 870.2300
Regulation Name: Physiological monitors network and communication system
Regulatory Class: Class II (Two)
Product Codes: MSX
Dated: March 22, 2011
Received: March 30, 2011

Dear Ms. Argaman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

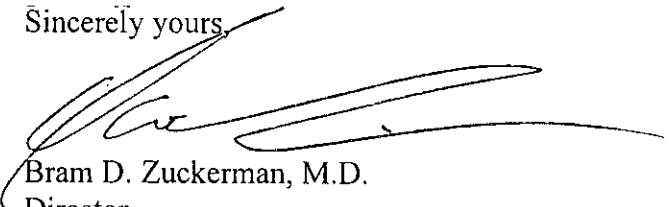
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or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K110521

Device Name: EverOn Central Display Station

Indications for Use:

The EverOn Central Display Station (CDS) is intended to provide secondary display of the information as displayed on multiple individual bed side monitoring units, on a central remote screen. The EverOn CDS is not intended to replace any part of the bed-side patient monitoring procedures. The system can be used in hospitals or hospital type and clinic environment.

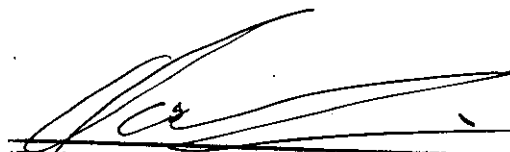
Prescription Use ✓
(Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(Part 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
for Division of Cardiovascular Devices

510(k) Number K110521